

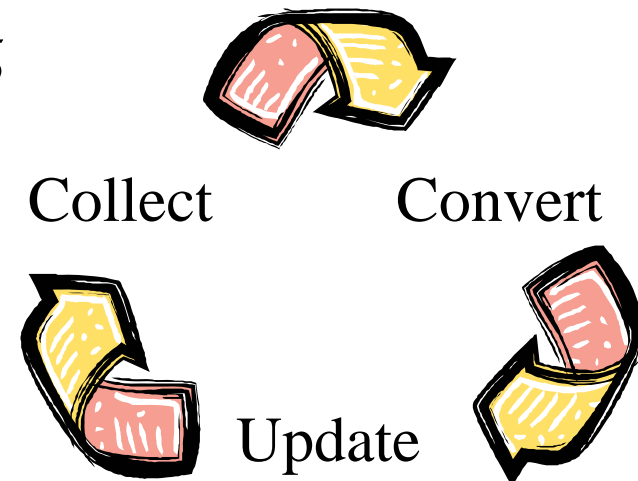
Outsourced SPL Conversion

Data Conversion Laboratory

www.dclab.com

Three Main Issues:

- Collection of Content for SPL
 - DPL, Establishment Registration, Text
- Conversion to SPL (XML)
 - Word / PDF / Quark / Excel to SPL (XML)
- Revisions of SPL
 - Changes to content of labeling
 - Changes to SPL standard





Collection of Content for SPL

- Draw on Internal Information Sources
 - Packaging
 - Regulatory (Forms 2656, 2657, 2658)
- Always done by the Sponsor

Conversion to SPL

- Copy & Paste
 - See www.dclab.com/cut_and_paste_conversion.asp
- Outsourced Conversion
 - By conversion vendor (DCL, Intagras, Reed, etc.)
 - By tool vendor (Glemser, i4i, Quark, ThinSpring, etc.)

But... remember XML is an open (non-proprietary) standard. Be leery of a vendor that says they are the **only** ones that can get it “right”





Revisions of SPL

- By conversion vendor
- By sponsor using tool

Criteria for Deciding Your Approach

- Expected Costs
- In-house XML and SPL Expertise
- Risks
- Volume
- Short-term Goals vs Long-Term Goals
- Schedule Requirements
- Turnaround Schedule
- Impact of Change



See www.dclab.com/fda_spl_requirements.asp

Market Leader in Content Conversion

- Active in SPL WG since '03
- Leader in data and content conversion since 1981
- Completed first large-scale SGML conversion (General Motors) and world's largest SGML conversion project (US Library of Congress)
- Authored the data conversion chapters in Goldfarb's *The XML Handbook* and in Kasdorf's *Columbia Guide to Digital Publishing*
- Frequent speaker on XML conversion



DCL Customers



Life Sciences

- GSK
- Merck
- Eli Lilly
- GE Medical / GE Healthcare
- British Medical Association



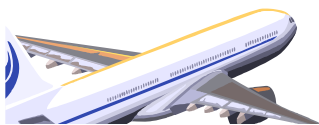
Technical Societies

- IEEE
- Society of Petroleum Engineers
- Water Environment Federation
- American Society for Metals



Defense

- Dept. of Defense
- Lockheed
- Boeing
- United Defense



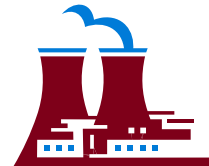
Aerospace

- Delta
- Gulfstream
- Bombardier
- Rolls Royce



Libraries

- Library of Congress
- NY Public Library
- Nat'l Library of Medicine
- Harvard Fine Arts Library



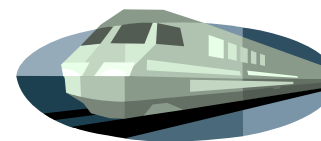
Utilities

- Duke Power
- GPU Nuclear
- NY Power Authority
- Iowa Electric Light



Technical Documentation

- Lucent
- Xerox
- General Electric
- Schlumberger
- Motorola



Transportation

- Washington METRO
- General Motors
- Freightliner
- Mercedes
- Saab



Heavy Machinery

- Case New Holland
- John Deere



DCL in SPL

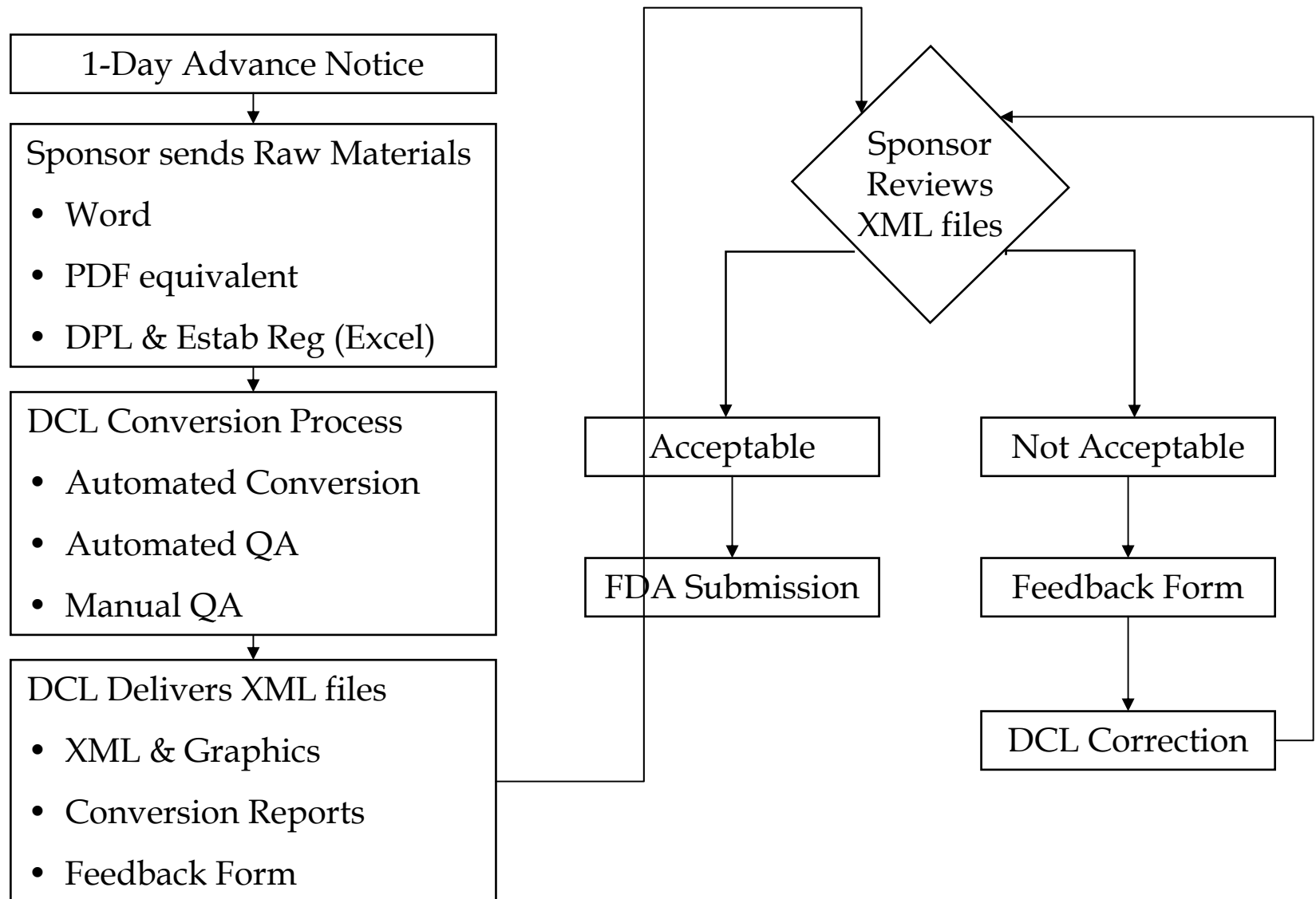
- Active participant in HL7 SPL Working Group
- Over 1500 PIs converted to SPL to date
 - 150+ sponsors
 - Data migration (in-house system)
 - SPL outsourced conversion
- Also working other XML initiatives
 - PIM
 - Standard Response Letters

Focus: Get it right the first time!

- “It’s the methodology”
- Conversion Specification
 - Documents the requirements
 - Based on FDA Implementation Guide
 - Serves as the basis for conversion and QA
- Conversion
 - Re-style to FDA standard
 - Automated conversion
- QA Check List
 - Mutual agreement on what is QA’d and how



Conversion Mechanics



Quality & Security

- Project Methodology builds in quality throughout
 - Multiple checkpoints keep conversion on-track
- Security is an integral part of our solution
 - SFTP file transfer ensures safe delivery
 - Internal project security ensures your materials are not confused with others
 - Secured facility with back-ups and disaster recovery



Process Validation

- We have completed a self validation covering the following items:
 - Overall Quality Management System, QA Program
 - Hardware/Software Infrastructure
 - Security Policies & Procedures
 - Software Development Methodology
 - Document Control and Training Records
 - Disaster Recovery, Backup and Contingency Planning
 - Customer Support Services

Training

- Training Required = Zero
 - We can implement a specification based on industry norms (how most sponsors are configuring their data) and our interpretation of the Implementation Guide
- But... a basic understanding of XML is very beneficial
 - To ensure that your solution meets internal objectives
 - To understand the implications of the conversion spec
- Training is available at multiple levels via 3rd parties
 - Generic XML
 - XML for Life Sciences





XML Validation

- DCL will provide a 'Conversion Report' that lists:
 - Metadata such as LOINC Codes, GUIDs, etc.
 - Drug Listing Data
- You can also...
 - Browse using Internet Explorer and FDA Stylesheet
 - How the FDA will view your XML
 - No cost option using existing tools
 - Different look / tags not exposed
 - Use XML Editor or Notepad
 - Most functional approach
 - Requires procurement and training



Updating your materials

- YOU Update XML using XML tool
 - XML Editor or SPL application
 - Achieved internally
 - No DCL involvement / cost
- WE revise XML based on your MS Word / Quark files
 - Based on revision tracking functionality
 - Low cost
 - Fast turnaround

Our Guarantee

- 100% Compliance to the FDA Schema
- 100% Acceptance of the Tagging & Structure
- And in the unlikely event of an error...
 - Fixing your XML instance is our 1A priority
 - at no cost to you
 - Fixing the process is our 1B priority
 - at no cost to you



Business Models

- Conversion cost probably less than you expect.
- Happy to share our business model with sponsors, not so much with competitors...
- Join us for a free 1-hour Webinar to learn
 - Business Models (Cost)
 - Schedule
 - QA Process Details
- Tuesday, March 3rd at 2PM EST for one hour
- Advance registration and approval is required
- Register at www2.gotomeeting.com/register/934031710



Thank You!

- Contact Information

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